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PCT/IN05/00063



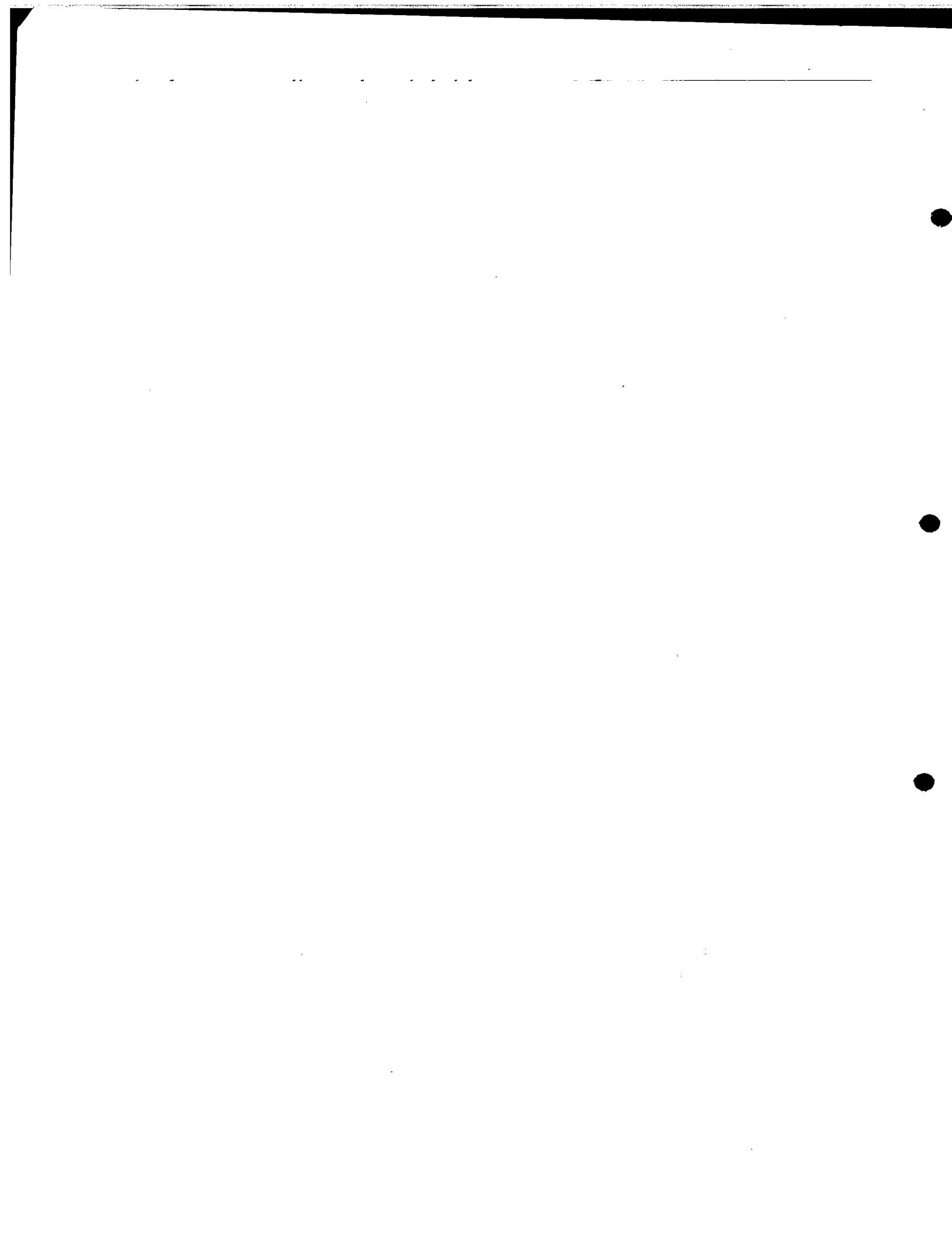
GOVERNMENT OF INDIA
MINISTRY OF COMMERCE & INDUSTRY
PATENT OFFICE, DELHI BRANCH
W - 5, WEST PATEL NAGAR
NEW DELHI - 110 008.

I, the undersigned being an officer duly authorized in accordance with the provision of the Patent Act, 1970 hereby certify that annexed hereto is the true copy of the **Application and Provisional Specification** filed in connection with Application for Patent No.226/Del/2004 dated 19th February 2004.

Witness my hand this 2nd day of May 2005.

A handwritten signature in black ink, appearing to read 'S.K. Pangasa'. Below the signature, the name is printed in capital letters.

Assistant Controller of Patents & Designs



0226 04
19 FEB 2004

Govt. of India Patent Office
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THE PATENTS ACT, 1970

(39 of 1970)

APPLICATION FOR GRANT OF A PATENT

[See Sections 5(2) 7, 54 and 135]

1. We 1) DEPARTMENT OF BIOTECHNOLOGY, of Block 2,
7th Floor, C.G.O. Complex
Lodhi Road, New Delhi-110 003;
2) MADHAV INSTITUTE OF TECHNOLOGY AND
SCIENCE, Gwalior

2. hereby declare-

(a) that I~~am~~ / We are in possessin of an Invention titledA DIAGNOSTIC KIT FOR DETECTING PULMONARY AND
EXTRA PULMONARY TUBERCULOSIS

Title

(b) that the Provisional / ~~Complex~~ Specification relating to
this invention filed with this application.(c) that there is no lawful ground of objection to the grant
of a patent to me / us.3. Further declare that the inventor(s) for the said invention
is / are :

- 1) PRAKASH SINGH BISEN, of Department of
Biotechnology, of Block 2, 7th Floor
C.G.O. Complex, an Indian national
2) RAM PRAMOD TIWARY, of Madhav Institute of Technology
and Science, Gwalior, an Indian national.

Surname
first and
then
name of
inventor/s

4. I/We, claim the priority from the application(s) filed in
convention countries, particulars of which are as follows :

NA

5. I/We state that the said invention is an improvement in or
modification of the invention the particulars of which are
as follows and of which I/We are the application/patentee:
NA

6. I / We state that the application is divided out of my/our application, the particulars of which are given below and pray that this application be deemed to have been filed on.....
NA
under section 16 of the act.
7. That I am / We are the assignee of the true and first inventors.

8. That my / our address for service in India is as follows :
L S DAVAR & CO.,

Monalisa, Flats IB & IC, 17, Camac Street,
Kolkata-700 017.
Phones : 247-3996, 247-5918, 280-5536
Fax No. : 91-33-247-5886, 240-6292
91-11-646-4443

9. Following declaration was given by the inventor(s) or applicant(s) in the convention country :
I / We the true and first inventors for this invention or the applicant(s) in the convention country declare that the applicant(s) herein is / are my / our assignee or legal representative.

Signature
of the true
and first
Inventor/s
or Applicant
In the convention
country
with date,
name to
be given
below
Signature

PRAKASH SINGH BISEN

RAM PRAMOD TIWARY

10. That to the best of my / our knowledge, information and belief the fact and matters stated herein are correct and that there is no lawful ground of objection to the grant of patent to me / us on this application.
11. Following are the attachment with application :
- (a) Provisional/Complete specification (3 copies).
 - (b) Drawings (Sheets) 3 copies. NA
 - (c) Priority document/s NA
 - (d) Statement and undertaking on Form 3 in dupl.
 - (e) Form 5. NA
 - (f) Power of Authority. To Follow
 - (g)
 - (h) 3000/-
 - (i) Fee Rs. 1,500/- Rs. 5,000/- in cheque / bank draft.
bearing No.....date...
on.....Bank.

To be
Signed by
applicant
or
authorised
patent
agent

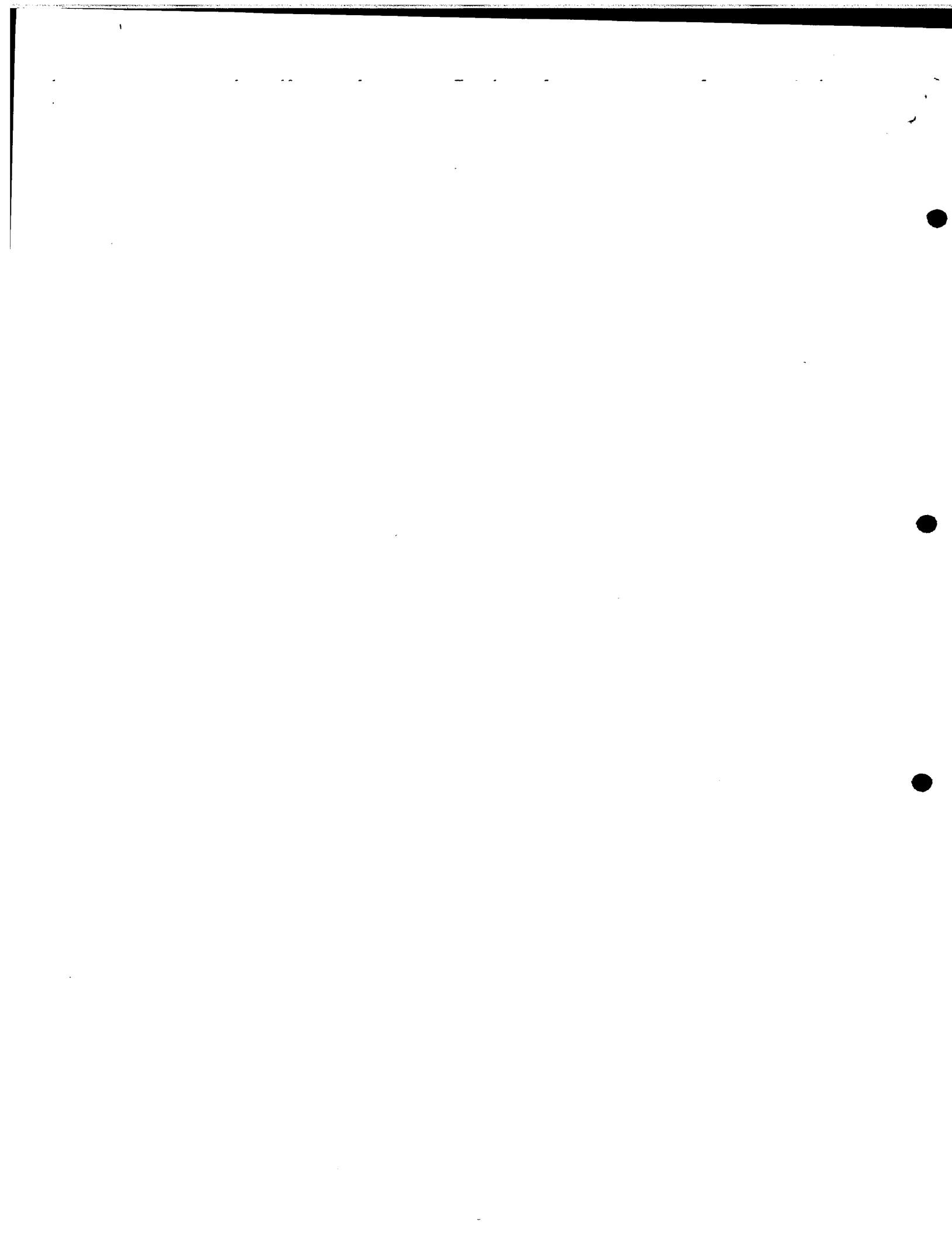
I/We request that a patent may be granted to me/us
for the said invention.

Dated this 11th day of February 2004

Signature (*S. Sanyal*)

of L. S. DAWAR & CO.
APPLICANTS' AGENT

To
The Controller of Patents
The Patent Office
at NEW DELHI



0226 04

FORM - 2

19 FEB 2004

THE PATENTS ACT, 1970

(39 of 1970)

PROVISIONAL/COMPLETE^X

SPECIFICATION

SECTION 10

TITLE

A DIAGNOSTIC KIT FOR DETECTING
PULMONARY AND EXTRA PULMONARY TUBERCULOSIS

APPLICANT

- 1) DEPARTMENT OF BIOTECHNOLOGY
of Block 2, 7th Floor, C.G.O. Complex
Lodhi Road, New Delhi-110 003
- 2) MADHAV INSTITUTE OF TECHNOLOGY AND
SCIENCE, Gwalior

The following specification particularly describes the nature of the invention and the manner in which it is to be performed

This invention relates to a diagnostic kit for detecting pulmonary & extra pulmonary tuberculosis.

Background of the invention

The conventional methods for detecting tuberculosis is time consuming & labour consuming AFB staining is considered to be insensitive (requiring 10,000 organism/ml of sputum for smear positive result with 100X microscope, refer Todar's Text Book of Bacteriology Online). ELISA-KP 90 is also known to be of low sensitivity and specificity (cut-off value >1.0 +ve, and <0.8 -ve test result) and requires sophisticated infrastructure as also the hypersensitivity based Tuberculin Skin Test (Montaux test) which lacks sensitivity and specificity in BCG vaccinated patient (Constantin P.et.al., Inf & Imm 1998;66). In the same way MYCODOOT is inconvenient for HIV correlated individuals (refer G.R.Somi et.al., Int J Tubercl and Lung Disease, 19999, vol 3) and Bactec-460 and Roche molecular system PCR based product) are though sensitive requires very costly infrastructure and technical expertise.

OBJECTS OF THE INVENTION

An object of this invention is to propose a diagnostic kit for detecting tuberculosis.

A further object of this invention is to propose a diagnostic kit which is economical and easy to handle.

A still further object of this invention is to propose a diagnostic kit based on liposome agglutination.

Another object of this invention is to propose a diagnostic kit which is sensitive and specific as it is based on a specific antigenic, antibody reaction.

Still another object of this invention is to propose a diagnostic kit which helps in fast detection of tuberculosis.

DESCRIPTION OF THE INVENTION

According to this invention there is provided a diagnostic kit for detecting pulmonary and extra-pulmonary tuberculosis.

In accordance to this invention there is provided a rapid liposome agglutination card test 'TB Screen' for in vitro diagnosis of pulmonary and extra pulmonary tuberculosis in which a suspension of antigenic epitopes selected from immunodominant regions of *Mycobacterium tuberculosis* will be intercalated into the bi-layer membrane of blue liposome particle (0.2-0.4 um). These will react with corresponding antibodies present in the specimen. It will result into agglutination of liposomes within 4 minutes that will appear as blue clumps against a white background of the test card.

The Positive and Negative Control raised in rabbits will also be provided as additional reagents with the test kit.

Dated this 11th day of FEBRUARY 2004



of L S DAVAR & CO.,
Applicants' Agent

